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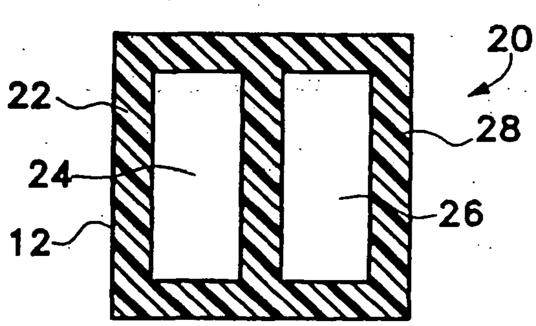
(54) Title: MULTI-SIDED CATHETERS



(57) Abstract: An improved catheter having an outer wall with multiple sides. The catheter can either be symmetrical having a cross-sectional shape such as a square, rectangle, pentagon or hexagon or be asymmetrical. The catheter can contain a single lumen or have multiple lumen, with various shapes possible for each lumen. The outer and inner walls of the catheter are varied in thickness in relation to the anticipated pressures. Thus, lumen that will be used for pressures exceeding blood pressure will have thinner walls and will depend on the pressure difference between the lumen and the blood vessel to hold the lumen open. Conversely, lumen that will be used for pressures lower than that of circulating blood will have thicker walls to resist collapse. The variable wall thickness allows for optimization of material utilized in the catheter while the multi-sided configuration imparts to the catheter a structural integrity component that assists in avoiding wall collapse and makes the catheter highly kink resistant.

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MULTI-SIDED CATHETERS

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to catheters, and more particularly to a catheter having a multi-sided cross-sectional shape and variable or modulated wall thickness.

2. Description of Related Art

In a progression of catheters ranging from single lumen catheters to multiple lumen catheters, the basic outside cross-sectional shape has remained circular. This can be attributed to many factors, including ease of manufacture, reduced trauma to the patient, and optimal flow characteristics. Particularly in a single lumen catheter, a circular cross section provides minimized frictional resistance to fluid flow due to the absence of restrictive areas in the lumen and achieves laminar flow under high flow pressures. Multiple lumen catheters, which are very useful in treatments such as hemodialysis due to the need for simultaneous infusion and withdrawal of fluids at high flow rates, also benefit from many of these stated advantages with respect to a circular cross-sectional shape.

Various designs for multiple lumen catheters have been created by dividing the circular outer cross-section of the catheter with one or more septa, creating two or more lumen. Examples of multiple lumen designs include a Circle-C lumen design and a Double-D lumen design. In the Circle-C lumen design, there exists a main lumen and a secondary lumen, which together form a circular shape. However, the secondary lumen is much smaller than the main lumen, which is C-shaped. The Double-D lumen design, on the other hand, has two equally sized lumen, created by bisecting the circular cross-section of a single lumen catheter with a septum. This design is the most commonly used and well-known in the hemodialysis industry.

Improvements to multiple lumen catheters have been addressed in a number of earlier patents. For example, catheter kinking was addressed by

Martin et al. in U.S. Patent No. 5,156,592, wherein the catheter, circular in cross-section, is pre-curved to conform to the shape of the incision typically formed in the body of the patient. However, because the cross-section of the catheter in **Martin et al.** is circular, there still exists the possibility of kinking and wall collapse when the device is implanted in the patient. **Hattler et al.** (U.S. Patent No. 4,406,656) sought to solve the problem of collapsing walls by providing walls that were initially collapsed. These collapsible walls should expand under the pressure of fluid flow therethrough, with the central lumen providing structural support for the catheter. While this device potentially eliminates the problem of kinking, the collapsibility of the walls may lead to other problems such as clotting when there is prolonged cessation of flow through a given lumen, as well as a potential for tearing because of the lack of wall thickness. In U.S. Patent No. 5,556,390 to **Hicks**, these same problems were addressed in a different manner by providing a catheter with one or more lumen which are oval, eliptical or oblong shaped. These luminal shapes allow the thickness of the outer wall and the septum to be much greater than in the prior art to avoid wall collapse. However, due to the circular cross-section of the outer wall of the catheter, wall collapse is still possible in designs involving more than two lumen, and the likelihood of kinking still remains.

Thus, there exists a need to provide a multi-lumen catheter in which the outer and inner wall thickness can be varied in relation to anticipated pressures. In addition, there exists a need to provide a multi-lumen catheter which will be highly kink resistant as well as resistant to wall collapse.

SUMMARY OF THE INVENTION

Accordingly, the present invention provides an improved catheter having an outer wall with multiple sides. The catheter can either be symmetrical having a cross-sectional shape such as a square, rectangle, pentagon or hexagon or be asymmetrical. The shapes impart a structural integrity component that assists in avoiding wall collapse and makes the catheter highly kink resistant. Whether the catheter has a single or multiple lumen configuration, the shape of each lumen is

widely variable. For instance, in a triple lumen catheter with a pentagonal cross-section, a primary lumen can be subdivided by a septum or septa into sublumen of either triangular or rhomboidal shape. There are numerous additional possibilities for the shapes of the lumen (sublumen), some of which are specifically illustrated in the drawings.

The outer and inner walls of the catheter can be varied in thickness in relation to the anticipated pressures. Thus, lumen that will be used for pressures exceeding blood pressure will have thinner walls and will depend on the pressure difference between the lumen and the blood vessel to hold the lumen open. Conversely, lumen that will be used for pressures lower than that of circulating blood will have thicker walls to resist collapse. This variable wall thickness allows for optimization of material utilized in the catheter and also imparts to the catheter a resistance to wall collapse.

These and other features and advantages of the present invention will become more apparent to those skilled in the art when taken with reference to the following more detailed description of the preferred embodiments of the invention and the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1A is a cross-sectional view of one embodiment of a four-sided catheter of the present invention with an essentially square lumen.

Fig. 1B is a cross-sectional view of another embodiment of a four-sided catheter of the present invention with dual rectangular lumen.

Fig. 1C is a cross-sectional view of another embodiment of a four-sided catheter of the present invention with dual rectangular lumen.

Fig. 2A is a cross-sectional view of one embodiment of a four-sided catheter of the present invention with dual triangular lumen.

Fig. 2B is a cross-sectional view of another embodiment of a four-sided catheter of the present invention with dual triangular lumen.

Fig. 2C is a cross-sectional view of a third embodiment of a four-sided catheter of the present invention with dual triangular lumen.

Fig. 2D is a cross-sectional view of a fourth embodiment of a four-sided catheter of the present invention with dual triangular lumen.

Fig. 3A is a cross-sectional view of a five-sided catheter of the present invention showing a dual lumen configuration.

Fig. 3B is a cross-sectional view of a five-sided catheter of the present invention showing a triple lumen configuration.

Fig. 3C is a cross-sectional view of another embodiment of a five-sided catheter of the present invention with a triple lumen configuration.

Fig. 4A is a cross-sectional view of a six-sided catheter of the present invention showing a dual lumen configuration.

Fig. 4B is a cross-sectional view of a six-sided catheter of the present invention showing a triple lumen configuration.

Fig. 4C is a cross-sectional view of another embodiment of a six-sided catheter of the present invention showing a dual lumen configuration.

Fig. 4D is a cross-sectional view of yet another embodiment of a six-sided catheter of the present invention showing a dual lumen configuration.

Fig. 5A is a cross-sectional view of a seven-sided assymetrical catheter of the present invention showing a dual lumen configuration.

Fig. 5B is a cross-sectional view of a seven-sided assymetrical catheter of the present invention showing a triple lumen configuration.

Fig. 6 is a cross-sectional view of a five-sided assymetrical catheter of the present invention showing a dual lumen configuration.

DETAILED DESCRIPTION OF THE INVENTION

The present invention satisfies the need for an improved catheter that exhibits resistance to kinking and wall collapse. In the detailed description that follows, it should be appreciated that like reference numerals are used to describe like elements illustrated in one or more of the figures.

Referring to Fig. 1A, a catheter **10** is shown with an outer wall **12** having a square-shape in cross-section. In this first embodiment, a single, large square-shaped primary lumen **14** passes through the middle of the catheter **10**, while two

smaller circular lumen **16** run adjacent to two corners of the catheter **10.** Conceptually a catheter is an outer wall surrounding a primary lumen. This lumen may be subdivided by a septum or septa into one or more sublumen. For convenience the sublumen are generally referred to as "lumen" herein. It should be appreciated in this embodiment as well as the examples given below that any number of smaller circular lumen can accompany the larger multi-sided lumen(s) in various locations throughout the catheter cross-section. These smaller lumen can be used for fluid flow, but are generally designated for guidewires to introduce the catheter into the bodily vessel.

Fig. 1B illustrates a catheter **20**, also possessing a square-shaped outer wall **12**. This embodiment has a dual lumen (sublumen) configuration including a first lumen **24** and a second lumen **26**. In this embodiment, the two lumen **24** and **26** are identical in size and shape, but either could vary in size depending on the particular application. Moreover, unique to this invention, the walls of the catheter can be varied in thickness. Thus, in Fig. 1B, if first lumen **24** was designated for pressures lower than that of circulating blood and second lumen **26** was designated for pressures exceeding blood pressure, a wall thickness **22** would be greater than a wall thickness **28**. Finally, Fig. 1C illustrates a catheter **30** with a third embodiment having the square-shaped outer wall **12** with rectangular lumen. In this embodiment, a guidewire lumen **38** runs through the center of the catheter **30** and has a first lumen **34** and a second lumen **36** on either side. As with the embodiment shown in Fig. 1B, the wall thickness of the catheter **30** is variable depending on the pressure flow through the lumen **34** and **36**.

Figs. 2A-2D illustrate further embodiments having the square-shaped outer wall **12**. However, in these embodiments, the primary lumen are triangular. In Fig. 2A, a catheter **40** is shown with a first triangular lumen **44** and a second triangular lumen **46**. As with the catheters **20** and **30** in Figs. 1B and 1C, respectively, the wall thickness of the catheter **40** is variable depending on the pressure designated for each lumen. Therefore, if the first and second lumen **44** and **46** are to be used for different purposes, requiring pressures above and below the blood circulation pressure, the walls **42** and **48**, which are adjacent to the first

and second lumen **44** and **46**, would be of different thickness. Fig. 2B shows a catheter **50** that differs slightly from the catheter **40** in that a guidewire lumen **58** is disposed in one of the corners of the catheter **50**, adjacent to both the first lumen **54** and the second lumen **56**. Fig. 2C illustrates a catheter **60** that has triangular lumen **64** and **66** of a slightly different configuration, in addition to two guidewire lumen **68**. Finally, Fig. 2D illustrates a catheter **70** that has a guidewire lumen **78** running through the center of the catheter **70** with first and second lumen **74** and **76** on either side.

Figs. 3A-3C illustrate a five-sided embodiment of the present invention. The pentagonal catheters have an outer wall **102** with five distinct sides. In Fig. 3A, catheter **100** has two similarly shaped lumen, first lumen **104** and second lumen **106**. These lumen eachhave four sides and conform to the outer wall **102** of the catheter **100**. As with the outer walls shown in the four-sided configurations in Figs 1 and 2, the walls of the pentagonal catheters shown in Fig. 3 have a variable thickness depending on the intended fluid pressure of the lumen to which they are adjacent. Fig. 3B shows a catheter **110** that contains a first, second and third triangular lumen **114, 116** and **118** respectively. Fig. 3C shows a catheter **120** that also contains three lumen, but the first lumen **124** and the third lumen **128** are rhomboidal in shape, having four sides, while second lumen **126** is pentagonal, possessing five sides.

In a six-sided embodiment of the present invention, Figs. 4A-4D illustrate various preferred configurations. All of the configurations of this embodiment have an outer wall **202** in the form of a hexagon with six distinct sides. As with the other embodiments above, these sides are shown with fairly sharp corners to emphasize the shape of each catheter. In actual practice, however, the transitions between facets may be somewhat more rounded. In Fig. 4A, a catheter **200** is shown with a first lumen **204** and a second lumen **206**. While these lumen are shown to be similar in shape, following the outline of the outer wall **202**, other possible configurations include two lumen that have a differing number of sides or that are circular. Fig. 4B illustrates a catheter **210**, containing three lumen, a first

lumen **214**, a second lumen **216** and a third lumen **218**, each having five sides. Fig. 4C, on the other hand, shows a catheter **220** with three lumen, each having four sides. Finally, in Fig. 4D, a hexagonal catheter **230** with the outer wall **202** is shown with two primary lumen, a first lumen **234** and a second lumen **236**. These two lumen **234** and **236** are configured to follow the outline of the outer wall **202** as well as to permit the passage of a guidewire lumen **238** through the center of the catheter **230**.

Figs. 5A, 5B and 6 illustrate embodiments of the present invention that have assymetrical outer walls. Figs. 5A and 5B are seven-sided configurations, while Fig. 6 is a 5-sided configuration. Fig. 5A illustrates a catheter **300** in cross-section having a first lumen **304** in the form of a pentagon, mirroring the outer wall portion to which it is adjacent, and a second lumen **306** in the shape of a rhombus, also mirroring the outer wall portion to which it is adjacent. While the two lumen are shown in Fig. 5 paralleling the outer wall **302**, it should be appreciated that other possibilities exist in the spirit of this invention. For example, one or both of the lumen could be circular or triangular, etc. Fig. 5B shows a multi-sided catheter **310**, also with outer wall **302**, but instead having three lumen **314, 316** and **318**. Again, while the lumen in this example are shown to parallel the walls to which they are adjacent, several shapes for the lumen are possible. Finally, Fig. 6 illustrates another assymetrical embodiment of the present invention, multi-sided catheter **400** with outer wall **402** having five sides with lumen **404** and **406**.

Many alterations and modifications may be made by those having ordinary skill in the art without departing from the spirit and scope of the present invention. For example, while catheters have been illustrated with two or three lumen, it should be apparent that the inventive concepts herein would be equally applicable to any number of lumen of various shapes and sizes. Moreover, the words used in this specification to describe the invention and its various embodiments are to be understood not only in the sense of their commonly defined meanings, but to include by special definition in this specification structure, material or acts beyond

the scope of the commonly defined meanings. Thus, if an element can be understood in the context of this specification as including more than one meaning, then its use in a claim must be understood as being generic to all possible meanings supported by the specification and by the word itself. The definitions of the words or elements of the following claims are, therefore, defined in this specification to include not only the combination of elements which are literally set forth, but all equivalent structure, material or acts for performing substantially the same function in substantially the same way to obtain substantially the same result.

CLAIMS

We Claim:

1. A multi-lumen catheter, comprising:
an outer catheter wall having more than three distinct sides;
a lumen defined by the outer catheter wall; and
a septum partitioning the lumen into at least two sublumen.

2. The multi-lumen catheter of Claim 1, wherein the septum defines a first sublumen and a second sublumen, wherein the outer catheter wall adjacent to the first sublumen has a wall thickness greater than that of the outer wall adjacent to the second sublumen.

3. The multi-lumen catheter of Claim 2, further comprising at least one guidewire lumen.

4. The multi-lumen catheter of Claim 2, wherein the first and second sublumen have substantially the same transverse cross-sections.

5. The multi-lumen catheter of Claim 1, wherein the septum defines at least three sublumen, wherein the sublumen have transverse cross-sections that contain an equal number of distinct sides.

6. A multi-lumen catheter, comprising:
an outer catheter wall having at least two substantially flat sides;
a lumen defined by the outer catheter wall; and
a septum partitioning the lumen into at least two sublumen.

7. A multi-lumen catheter, comprising:

an outer catheter wall having a symmetrical cross-sectional shape, wherein the shape is selected from the group consisting of a square, a pentagon, a hexagon, a heptagon or an octagon;

a lumen defined by the outer catheter wall; and

a septum partitioning the lumen into at least two sublumen.

8. A multi-lumen catheter, comprising:

an outer catheter wall having an asymmetrical cross-sectional shape containing at least two substantially flat sides;

a lumen defined by the outer catheter wall; and

a septum partitioning the lumen into at least two sublumen.

9. A multi-lumen catheter, comprising:

an outer catheter wall having a transverse cross-section that does not contain an arcuate portion;

a lumen defined by the outer catheter wall; and

a septum partitioning the lumen into at least two sublumen.

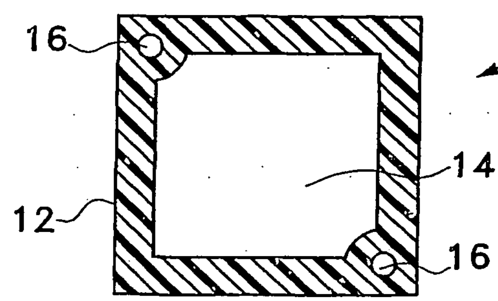

Fig. 1A

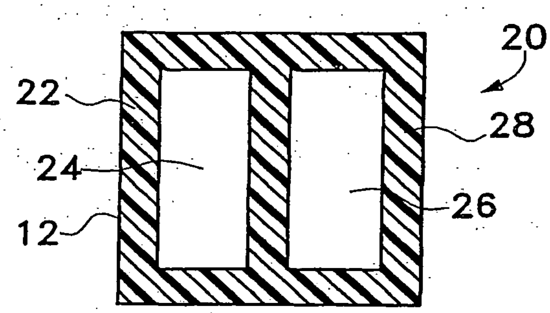

Fig. 1B

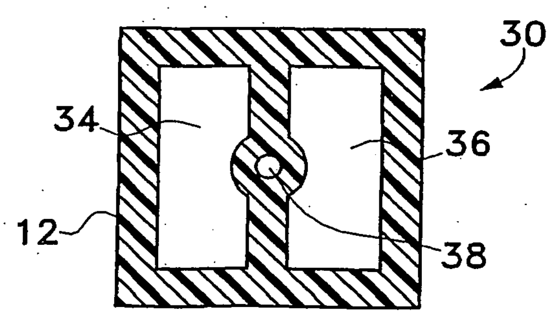

Fig. 1C

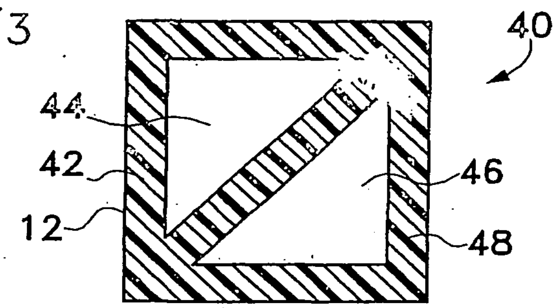

Fig. 2A

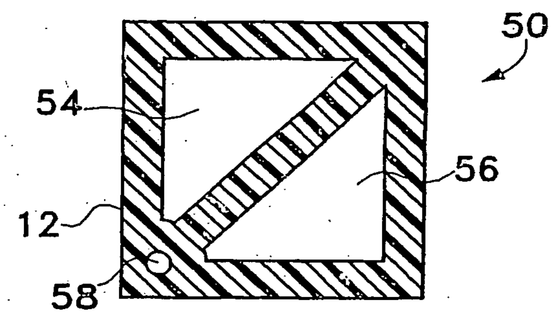

Fig. 2B

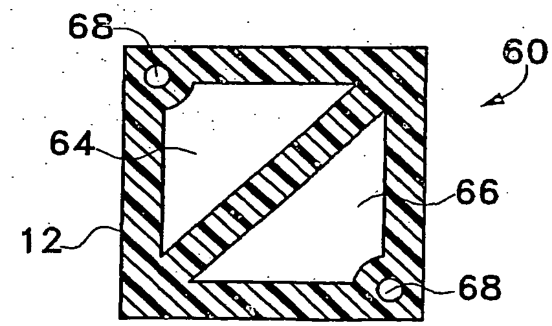

Fig. 2C

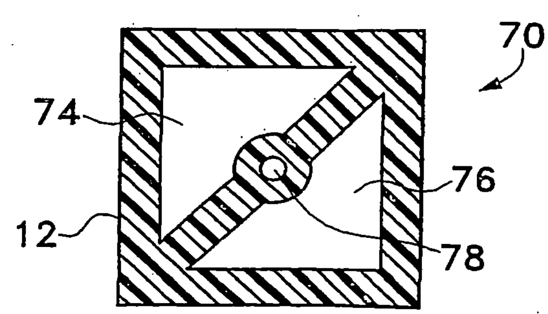

Fig. 2D

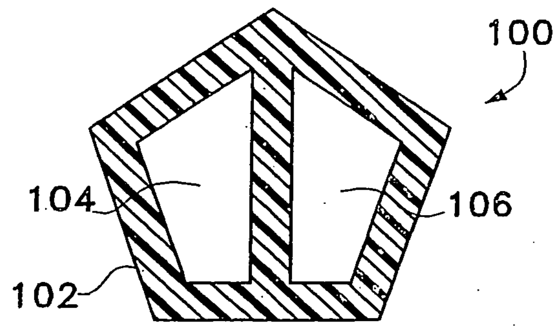

Fig. 3A

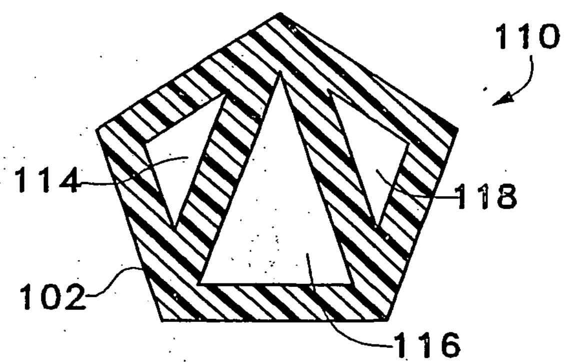

Fig. 3B

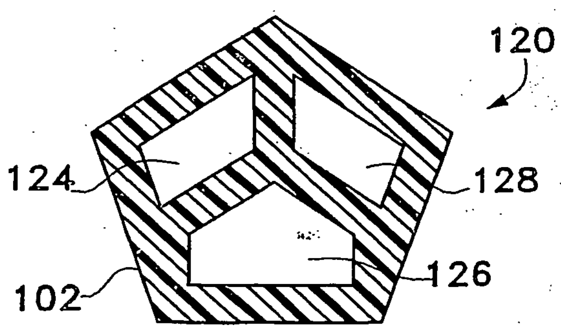

Fig. 3C

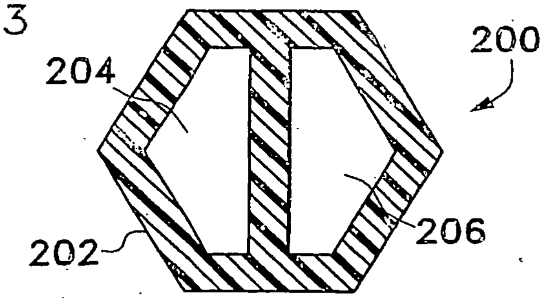

Fig. 4A

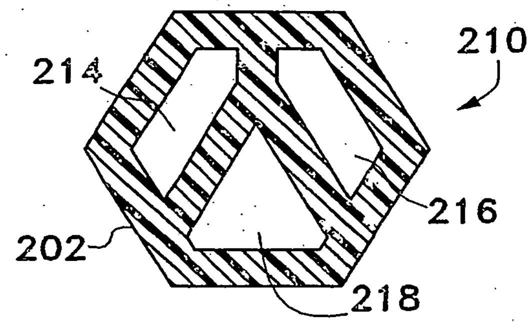

Fig. 4B

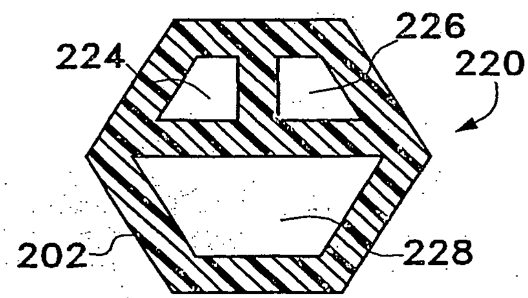

Fig. 4C

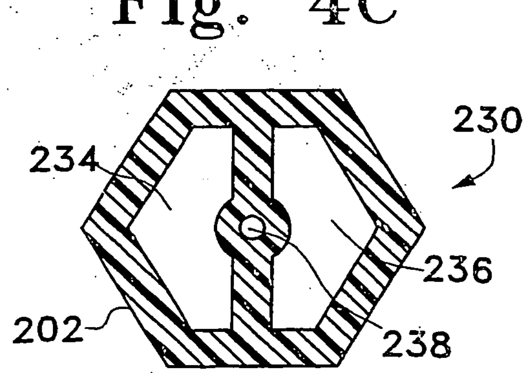

Fig. 4D

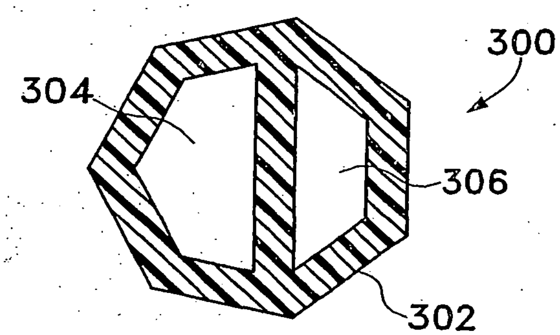

Fig. 5A

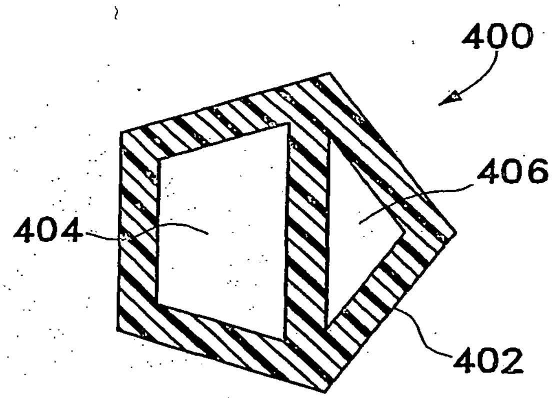

Fig. 6

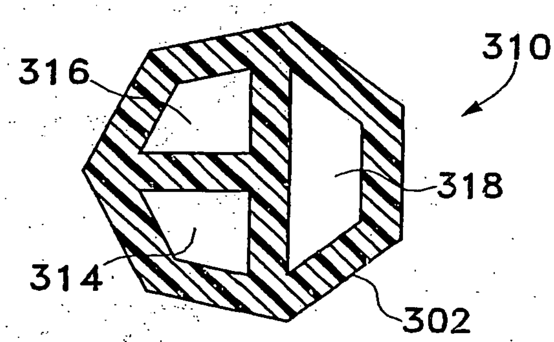

Fig. 5B

INTERNATIONAL SEARCH REPORT

International Application No
PC1/US 01/25619

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M25/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	US 4 619 643 A (BAI CHAO-LIANG) 28 October 1986 (1986-10-28) column 8, line 36 - line 64; figures	1,4,6,8 7,9
A	US 5 830 196 A (HICKS ALLEN J) 3 November 1998 (1998-11-03) column 6, line 50 -column 7, line 12; figures	1-9
A	US 5 556 390 A (HICKS ALLEN J) 17 September 1996 (1996-09-17) cited in the application abstract; figures	1-4,6-9
A	FR 1 285 953 A (EYNARD & CIE J) 2 March 1962 (1962-03-02) the whole document	1,6-9

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
14 January 2002	21/01/2002

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Kousouretas, I

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Inte[illegible]al Application No
PCT/US 01/25619

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	FR 2 240 026 A (RHONE POULENC SA) 7 March 1975 (1975-03-07) page 2, line 5 -page 3, line 16; figures	1,6-9
A	US 4 307 723 A (FINNEY ROY P) 29 December 1981 (1981-12-29) abstract; figures	1,6-9
A	DE 296 20 135 U (CONVIMED GMBH MEDIZINISCHER VE) 13 February 1997 (1997-02-13) claims; figures	1,6-9

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

ɔrmation on patent family members

Inter nal Application No
PCT/US 01/25619

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
US 4619643	A	28-10-1986	NONE		
US 5830196	A	03-11-1998	AU	7161696 A	09-04-1997
			EP	0861099 A1	02-09-1998
			JP	11512625 T	02-11-1999
			WO	9710858 A1	27-03-1997
			AU	725885 B2	26-10-2000
US 5556390	A	17-09-1996	NONE		
FR 1285953	A	02-03-1962	NONE		
FR 2240026	A	07-03-1975	FR	2240026 A1	07-03-1975
US 4307723	A	29-12-1981	US	4212304 A	15-07-1980
			CA	1112119 A1	10-11-1981
			DE	2905703 A1	11-10-1979
			DE	7904093 U1	08-04-1982
			FR	2421625 A1	02-11-1979
			GB	2018600 A ,B	24-10-1979
DE 29620135	U	13-02-1997	DE	29620135 U1	13-02-1997